

ARTICLE 20:51

PHARMACISTS

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CHAPTER 20:51:15

PHARMACIES IN HOSPITALS, NURSING FACILITIES, OR RELATED FACILITIES

Section

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20:51:15:01. Definition and general provisions Definitions. ~~Definitions and general provisions used in this chapter are as follows~~ Terms used in this chapter mean:

(1) ~~"24-Hour~~ After-hours central pharmacy, " a pharmacy that provides pharmacist services via electronic means to a healthcare facility with limited on-site pharmacist service hours;

(2) ~~(4)~~ "Compounding," the taking of two or more measured ingredients, and by simple or complicated means, depending on the nature of the ingredients, fabricating them into a single preparation, usually referred to as a dosage form;

(3) ~~(5)~~ "Dispensing," ~~includes, but is not limited to,~~ issuing to a patient, or to a person acting on a patient's behalf, one or more unit doses of medication in a suitable container with appropriate labeling. Dispensing affects one or many patients. Dispensing, while including compounding, also includes the act of packaging a drug or medication either from a bulk container, or as a result of compounding, in a container other than the original and labeling the new container with all required information;

~~(4)~~ ~~(7)~~ "Hospice program," a coordinated program of inpatient services providing palliative rather than curative care for a patient;

~~(5)~~ "Off-site pharmacy," any pharmacy receiving after-hours central pharmacy services;

~~(6)~~ "Original container," a container which has been packaged by a licensed manufacturer and which is labeled in compliance with federal and South Dakota law;

~~(7)~~ ~~(1)~~ ~~The terms "part time,"~~ "Part-time," "limited," or "conditional" pharmacy, ~~mean the~~ providing of ~~pharmaceutical pharmacy~~ services by a registered pharmacist under a pharmacy license issued by the ~~South Dakota Board of Pharmacy~~ board on less than a full-time operation basis, in hospitals, nursing facilities, and related facilities and where such ~~pharmaceutical pharmacy~~ services are limited to ~~inpatients~~ patients registered at the facility;

~~(8)~~ ~~(3)~~ ~~The term "pharmaceutical~~ Pharmacy services," means and includes:

(a) The ~~conduct~~, operation, management, or control of a pharmacy; or

(b) Preparing, compounding, processing, packaging, labeling, or dispensing one or more doses of medication ~~either~~ upon prescription of an authorized practitioner for subsequent administration to, or use by, a patient; or

(c) Any other act, service, operation, or transaction incidental to or forming a part of any of the acts in the ~~above subdivisions~~ ~~(1)~~ subsections (a) and (2) ~~(b)~~ requiring, involving, or employing the science or art of any branch of the ~~pharmaceutical~~ profession of pharmacy, study, or training;

~~(9)~~ ~~(2)~~ "Pharmacist," a person licensed by the ~~South Dakota State Board of Pharmacy~~ board, to ~~prepare, compound, and dispense physicians' prescriptions, drugs, medicines, and poisons, and whose license has not been revoked or suspended;~~ engage in the practice of pharmacy.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-33.

20:51:15:18. After-hours pharmacy services. A hospital pharmacy, nursing facility pharmacy, or other healthcare facility pharmacy may contract with another central pharmacy to provide pharmacy services via electronic means. Contracting for after-hours pharmacy services does not relieve the hospital pharmacy, nursing facility pharmacy, or other healthcare facility pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. An off-site pharmacy contracting with a central pharmacy may not reduce pharmacist staffing without board approval.

The contract shall identify and secure a qualified pharmacist to be available at the central pharmacy location to review prescription orders, consult and approve and/or provide medications beyond normal off-site pharmacy hours.

A central pharmacy located in another state immediately adjoining South Dakota may contract to provide central pharmacy services to a hospital in South Dakota if that South Dakota hospital is part of a healthcare system located outside of South Dakota.

Any central pharmacy located outside of South Dakota that provides pharmacy services to an off-site pharmacy in South Dakota must be licensed by the board.

Any central pharmacy pharmacist that performs any pharmacy service functions for an off-site pharmacy in South Dakota must be licensed by the board.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1)(4), 36-11-33.

20:51:15:19. Implementation of after-hours central pharmacy services. An after-hours central pharmacy service agreement must be approved by the board and meet all the following requirements:

- (1)Each pharmacist-in-charge must make application to use or provide after-hours central pharmacy service;

- (2) The pharmacist-in-charge at each off-site pharmacy and after-hours central pharmacy must present written policies and procedures for following the requirements of § 20:51:20 and must meet state and federal pharmacy regulations;
- (3) If the off-site pharmacist has made application to utilize an automated mechanical distribution device (AMDD) to provide medications, a pharmacist must be present at the pharmacy a minimum of once weekly to adequately supply medications to the AMDD and maintain required records;
- (4) If the off-site pharmacy does not use AMDDs, a pharmacist must be present on a daily basis (excluding weekends and holidays) to adequately supply medications and maintain required records.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-33.

20:51:15:20. Other requirements for after-hour central pharmacy service.

1. The pharmacy providing after-hours central pharmacy service must have reasonable and appropriate pharmacist staffing to provide quality patient care at either facility;
2. There must be initial and on-going training of the central pharmacy service pharmacists to demonstrate competency and qualifications to provide effective off-site pharmacy services;
3. Pharmacists at the central service pharmacy must receive a copy of the physician's original medication orders via facsimile or electronic transmission;
4. Pharmacists at the central service pharmacy must be able to review the inpatient and/or ambulatory patient profile for:
 - a. Medication history;
 - b. Diagnosis;
 - c. Allergies;

- d. Patient data – weight, age, height, etc.:
- e. Duplication of drugs;
- f. Potential drug interactions;
- g. Adverse drug reactions;
- h. Lab information; and
- i. Other pertinent information.

5. Before any medication is removed from the off-site pharmacy, floor stock, or an automated dispensing device, the central pharmacist must review all prescription or medication orders unless the clinical condition of the patient is such that a delay in therapy will cause harm to the patient. This must be documented either electronically or by initials of the central service pharmacist. Records must be kept for two years.

6. The central service pharmacist must have the ability to contact the prescriber to discuss any concerns identified during the pharmacist review of the patient information.

7. The central service pharmacy must have adequate references to answer questions in a timely manner including, but not limited to the off-site pharmacy's:

- a. Appropriate policies and procedures;
- b. Standard drug concentrations or drug protocol;
- c. Formulary information;
- d. Contact phone numbers at the patient care areas.

8. The central pharmacy shall provide a 24-hour telephone number to the patient care areas of the off-site pharmacy;

9. An electronically generated medication administration record (MAR) must be verified by the off-site registered nurse.

Source:.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-33.

CHAPTER 20:51:30

TELEPHARMACY

Section

<u>20:51:30:01</u>	<u>Definitions.</u>
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<u>20:51:30:05</u>	<u>License renewal.</u>
<u>20:51:30:06</u>	<u>Physical requirements.</u>
<u>20:51:30:07</u>	<u>Staffing requirements.</u>
<u>20:51:30:07.01</u>	<u>Technician and intern staffing requirements.</u>
<u>20:51:30:07.02</u>	<u>Pharmacist-to-technician ratio.</u>
<u>20:51:30:07.03</u>	<u>Reporting requirements.</u>
<u>20:51:30:07.04</u>	<u>Prescription workload.</u>
<u>20:51:30:07.05</u>	<u>Requirements for prescription orders.</u>
<u>20:51:30:08</u>	<u>Requirements for operation.</u>
<u>20:51:30:09</u>	<u>Routine quality assurance required.</u>
<u>20:51:30:10</u>	<u>Use of automated mechanical dispensing device (AMDD)</u>

20:51:30:01. Definitions. Terms used in this chapter mean:

- (1) “Automated mechanical distribution device,” as defined in § 20:51:17:01;
- (2) “Central pharmacy,” as defined in SDCL 36-11-71(1);
- (3) “Medical clinic” or “community health center”, a facility which has, on staff, one or more practitioners licensed under either SDCL 36-9A-12 or 36-4A-22 or 36-9A-13;

- (4) “Real time,” the transmission of information through data, video, and audio links that is so rapid that the information is available to the central pharmacy and remote pharmacy simultaneously;
- (5) “Remote pharmacy,” as defined in SDCL 36-11-71(2);
- (6) “Telepharmacy practice,” as defined in SDCL 36-11-71(3);
- (7) “Unit of issue package,” as defined in §20:51:21:01(11).

Source:

General Authority: SDCL 36-11-11(1), 36-11-71(2), and (3).

Law Implemented: SDCL 36-11-11(1), (4), (5), and 36-11-71.

20:51:30:02. Application for remote pharmacy site. An application for licensure to establish, operate, or maintain a remote pharmacy shall be made on a form provided by the board and must be submitted to the board at least 60 days prior to opening the remote pharmacy. Documentation showing that all requirements of this chapter have been met must be submitted with the application. A set of blueprints shall be provided to the board with the application for licensure. The initial license fee for a remote pharmacy is \$200.

No permit to conduct a remote pharmacy may be issued if a community pharmacy is located in the same community as the remote site. For the purposes of this rule, “community” is defined as that area within a distance of 20 miles. (This distance requirement is consistent with federal standards for medically underserved areas.)

The board at its discretion may allow for a variance to this distance requirement.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72(1).

Law Implemented: SDCL 36-11-72(1).

20:51:30:03. Ownership or control by pharmacist required. No permit to conduct a remote pharmacy may be issued to any pharmacist applicant unless such pharmacist applicant is owner, or part owner, of the place of business for which telepharmacy registration is applied, or unless the non-pharmacist owner of the place of business for which the telepharmacy registration

is applied for, has made affidavit on a form prescribed by the board delegating full and complete authority to the pharmacist applicant to be in active management of the place of business for the license year ending June 30.

The board shall be notified at least 10 days before any change of pharmacist-in-charge.

The license for the remote pharmacy is not transferable.

Source:

General Authority: SDCL 36-11-11(1), 36-11-34), and 36-11-72(1).

Law Implemented: SDCL 36-11-34 and 36-11-72.

20:51:30:04. Board inspection. Before any remote pharmacy site shall open for service, the board shall inspect the remote pharmacy for minimum equipment, size, security, and sanitation standards as set forth in § 20:51:07:01.

Source:

General Authority: SDCL 36-11-11(1), (4), (5), and 36-11-72(2).

Law Implemented: SDCL 36-11-71(2) and 36-11-72(2).

20:51:30:05. License renewal. Every remote pharmacy license expires on June 30 of each year and may be renewed annually by filing an application provided by the board. The renewal fee is \$200.

Renewals postmarked after June 30 are subject to a late fee of \$100 in addition to the renewal fee.

Source:

General Authority: SDCL 36-11-11(1), (4), and (5).

Law Implemented: SDCL 36-11-72(1).

20:51:30:06. Physical requirements. The remote pharmacy remote site is considered an extension of the central pharmacy. This applies even though the remote pharmacy is required to be licensed as a pharmacy. The following requirements apply to remote pharmacies and central pharmacies:

(1) There must be a continuous, two-way audiovisual link between the central pharmacy and the remote site. The video camera used for the certification of prescriptions must be of sufficient quality and resolution so that the certifying pharmacist can visually identify the markings on tablets and capsules. Unless the camera used to certify prescriptions can also be used to monitor activities in other parts of the remote site, a second camera is required. A security camera trained on the entire dispensing area shall be sufficient to meet the requirements;

(2) Only a licensed central pharmacy located in South Dakota may operate remote telepharmacy sites in South Dakota;

(3) Each remote site shall display a sign easily viewable by customers stating “This business is a remote pharmacy, supervised by a pharmacist located at (*insert name of pharmacy and address*)”;

(4) The remote pharmacy dispensing area shall be posted as a “restricted area.” Only pharmacy technicians or pharmacy interns employed directly and involved in processing prescriptions are permitted in the dispensing area;

(5) There must be restricted access to the “restricted area”. The security system at the remote pharmacy must allow for tracking of entries into the pharmacy. The pharmacist-in-charge shall review the log of entries at least weekly.

(6) The remote pharmacy shall provide a toll-free telephone number that patients can use to contact the central pharmacy and shall be printed on the label of each prescription container. Toll-free numbers must also be available to prescribers attempting to phone prescription orders into a remote pharmacy since the prescriber will need to phone new orders directly to the central pharmacy.

Source:

General Authority: SDCL 36-11-11(1)) and 36-11-72.

Law Implemented: SDCL 36-11-11(1) and 36-11-72(3).

20:51:30:07. Staffing requirements. Any pharmacist performing services in support of a remote pharmacy, whether those services are performed at the central pharmacy or the remote pharmacy, must be licensed by the board. A copy of the pharmacist's license must be posted in any remote pharmacy to which the pharmacist provides services.

Source:

General Authority: SDCL 36-11-11(1)) and 36-11-72(3).

Law Implemented: SDCL 36-11-13 and 36-11-72(3).

20:51:30:07.01. Technician and Intern staffing requirements. All remote sites must be staffed with South Dakota registered pharmacy technicians or interns. A technician working at a remote site shall have a minimum of one year or 2000 hours of experience as a registered pharmacy technician and shall be certified through one of the certification programs recognized by the board.

Source:

General Authority: SDCL 36-1-11(1) and 36-11-72(3).

Law Implemented: SDCL 36-11-72 (3).

20:51:30:07.02. Pharmacist-to-technician ratio. The pharmacist on duty at a central pharmacy may supervise no more than the number of technicians allowed in accordance with § 20:51:29:19. The total number of allowed technicians may be divided between the central and remote pharmacies in any manner provided. However, each remote site must have at least one technician or intern on duty when it is open.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:07.03. Reporting requirements. It shall be the duty of the pharmacist-in-charge to maintain and report to the board any dispensing errors or any issues related to staffing or patient safety.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72(4).

Law Implemented: SDCL 36-11-72(2) and (4).

20:51:30:07.04. Prescription workload. Any central pharmacy providing telepharmacy services shall provide adequate pharmacist staffing to meet the prescription workload of both the central and remote pharmacies.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:07.05. Requirements for prescription orders. Only a registered pharmacist may take a verbal prescription order. A pharmacy technician at the remote pharmacy may not accept verbal orders for new prescriptions, but may accept written orders. A written order for a new prescription must be entered at the central pharmacy unless the remote site uses pharmacy software that requires a pharmacist to override all drug utilization review alerts.

Source:

General Authority: SDCL 36-11-11(1), 36-11-14 and 36-11-72.

Law Implemented: SDCL 36-11-14 and 36-11-72.

20:51:30:08. Requirements for operation. The following requirements must be adhered to when operating a remote pharmacy:

(1) The remote pharmacy may only be open if all links with the central pharmacy are functioning properly. If all links are not functioning properly, the remote pharmacy must be closed unless a pharmacist is working at the remote pharmacy;

(2) No remote site may be open when the central pharmacy is closed, unless a licensed pharmacist is working at the remote site;

(3) All prescriptions filled at the remote pharmacy must be profiled, reviewed, and interpreted by a pharmacist at the central pharmacy before the prescription is dispensed;

(4) All remotely dispensed medications must have a label properly prepared in accordance with § 20:51:05:21 and attached to the final drug container before the pharmacist certifies the dispensing process. This prescription certification process must be done using a real-time, two-way audiovisual link. All prescription certification must be documented in the computer record. The computer must be capable of carrying the initials of the technician preparing the prescription and the pharmacist verifying the prescription. Verification of the prescription is required for both new and refills;

(5) When the patient receives a prescription, the pharmacist must use audiovisual communication to counsel the patient regarding use of the prescription being dispensed. Counseling is required only for new prescriptions. The pharmacist must meet the counseling standards in accordance with § 20:51:25:04;

(6) The remote site must maintain a log, signed by the patient, which documents a patient's refusal for counseling by the pharmacist.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72.

Law Implemented: SDCL 36-11-72.

20:51:30:09. Routine quality assurance required. Telepharmacy applicants shall develop, implement, and periodically review written policies and procedures consistent with this chapter. All staff must be fully trained and show adequate knowledge of the policy and procedures to govern a remote telepharmacy. Policy and procedures must be reviewed annually and be signed by both the technician at the telepharmacy and the pharmacist-in-charge at the central pharmacy.

All revisions to policy and procedures made after initial board approval shall be resubmitted to the board for approval.

The pharmacist-in-charge must adhere to the following procedures:

- (1) Inspect the remote pharmacy at weekly intervals or more if deemed necessary.

Inspection must be documented and kept on file at the remote pharmacy and available upon request by the board;

- (2) Implement and conduct a quality assurance plan. Controlled substance prescriptions shall be verified for both accuracy and legitimacy of the original prescription by the pharmacist-in-charge or a designated pharmacist during weekly inspection visits;

- (3) Report all incidents to the board along with a written plan for corrective action;

- (4) Maintain records of all controlled substances stocked by the remote pharmacy through a daily perpetual inventory. Controlled substance perpetual inventory records must be available for inspection by the board's inspectors. A remote pharmacy stocking controlled drugs must be registered by the DEA and South Dakota Department of Health Licensing and Certification;

- (5) Conduct an inventory of all controlled substances at least monthly to verify accuracy. DEA 222 required records must be available for inspection at the registered site where medications are received and stored.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72.

Law Implemented: SDCL 36-11-72.

20:51:30:10. Use of automated mechanical dispensing device (AMDD). If the remote site uses an automated prepackaged distribution system, the stocking and loading of this system must either be checked by a pharmacist, prior to use, or employ a secure bar coding system or its equivalent. Policies and procedures consistent with § 20:51:17 regarding the operation of the automated mechanical distribution system must be developed and submitted to the board for consideration. After approval, these policies and procedures must be available at both the central pharmacy and the remote pharmacy.

Source:

General Authority: SDCL 36-11-11(1), (6) and 36-11-72(6).

Law Implemented: SDCL 36-11-11(6) and 36-11-72(6).